Attorney Docket No.: 5565.214-US PATENT

Express Mail Label No. EV 409531611 US

## **REMARKS**

Reconsideration and allowance are respectfully requested.

Claims 1, 4, 5, and 7-10 are pending and at issue. In this response, claims 1, 4, and 5 are amended to clarify the Kex2 enzymatic activity of the endoprotease required by the claim. Support for the amended claims can be found in the specification and claims as originally filed; no new matter is added.

## Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1, 4, 5, and 7-10 have been rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. The Examiner contends that the metes and bounds of enzymes that are "about 90% homologous" to Kex2 are unclear, and that the terms "derived from" and "variant" are indefinite. These rejections are respectfully traversed.

In this response, claim 1 has been amended to specify that the enzyme required by the claim must exhibit Kex2 enzymatic activity. Applicants have previously pointed out that the specification clearly defines Kex2 enzymatic activity (at page 3, lines 21-30) and provides three examples of proteins having Kex2 enzymatic activity: Kex2 itself; a carboxyterminally-truncated form of Kex2; and a Kex2 to which has been added an endoplasmic reticulum-specific retention signal. It is respectfully submitted on this basis that the present claims are definite and that this rejection may be withdrawn.

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In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Commissioner is hereby authorized to charge any fees in connection with this application and to credit any overpayments to Deposit Account No. 14-1447. The Examiner is invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: July 14, 2004

Reza Green, Reg. No. 38,475

Novo Nordisk Pharmaceuticals, Inc.

100 College Road West Princeton, NJ 08540

(609) 987-5800

Use the following customer number for all correspondence regarding this application 23650

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Marked-up version of claims showing changes

1. (Twice amended) A method for producing Factor VII comprising (a) cultivation of a

mammalian cell line comprising a DNA sequence encoding a [yeast-derived endoprotease]

Kex2 variant having Kex2 enzymatic activity and a DNA sequence encoding Factor VII

(FVII) in a suitable culture medium, under conditions in which both said endoprotease and

said FVII are expressed; and (b) isolation of Factor VII from the medium.

4. (Amended) The method of claim 3 wherein the [yeast Kex2 like endoprotease] Kex2

<u>variant</u> is C-terminally truncated <u>Kex2</u> and has no transmembrane region.

5. (Amended) The method of claim 4, wherein the [yeast Kex2 like endoprotease] Kex2

variant has an ER retention signal added to the C-terminal end.

- 5 -